

## REMARKS/ARGUMENTS

Applicant filed an Amendment dated March 16, 2010 which amended independent claims 1, 12, and 14 to specifically state "*means for giving rise to a continuously replenished rising layer filtered air over the work surface and forming a robust blanket of sterile air over the work surface*". In the Advisory Action dated March 30, 2010, the Examiner indicated that the Amendment was not entered because it would require further search and/or consideration. Applicant has now filed a Request for Continued Examination (RCE), and re-submits the same claim amendments to independent claims 1, 12 and 14. In addition, Applicant has filed new dependent claims 22 and 23 which define additional novel, nonobvious subject matter.

### Robust Blanket of Sterile Air

In the Advisory Action, the Examiner indicated that the request for reconsideration had been considered but did not place the application in condition for allowance because in the Examiner's opinion the term "robust blanket" is not equivalent to layers of air that are parallel with the work surface. Applicant respectfully disagrees. While the Examiner is correct that the term "robust" is commonly known to mean full of strength, fullness or full bodied, the Examiner has not acknowledged the term "blanket". The plain and ordinary meaning of a "blanket" is a covering layer. The phrase "blanket of sterile air" is used in the claims and in the patent specification in accordance with this plain and ordinary meaning.

In the claims, the "robust blanket of sterile air" is formed over the horizontal work surface. This is simply another way of articulating that a robust layer of sterile air is formed over the work surface. In fact, the claim language specifically requires that the recited means gives rise to a continuously replenished rising *layer of filtered air over the work surface* and that this rising layer of filtered air forms the robust blanket of sterile air over the work surface.

The claims as amended describe the invention as it is described in the specification. See, for example, paragraphs [0008] and [0009] which state:

The sterile/filtered air is directed across the work surface from all directions inwardly of the boundary wall and forms a continuously replenished rising

*layer of filtered air over the work surface* within the sterile zone/volume defined by the boundary wall. The continuously replenished rising layer of filtered air prevents any inflow/entrainment of contaminants into the sterile zone.

Compared to the prior configurations of sterile air trolley, the working surface in the apparatus of the present invention is protected by *a sterile air layer that is robust* while not significantly constricting the available work surface area or impeding access to it.

In paragraphs [0014] and [0033], the specification refers to maintaining a robust blanket of sterile air over all of the surgical implements placed on the work surface 12. Paragraph [0030] of the specification explains that the filtered air flows through air outlets facing inwardly from the boundary wall to direct the air inwardly generally towards the center of the tray (i.e., work surface). As the air flow from all four sides merge, it rises as a column. This is the continuously replenished rising *layer* of filtered air described in the independent claims. It provides a sterile air zone for surgical implements placed on the work surface.

The robust blanket or layer of air described in the patent is clearly different from the turbulent vortex described in the Marsh '999 reference. Respectfully, the meaning of the claim language is definite, well supported by the specification, and clearly defines over the prior art of record.

**No Prima Facie Case of Obviousness**

The applied prior art Howorth U.S. 4,531,956 and Marsh et al. U.S. 3,629,999 do not provide adequate basis for a prima facie case of obviousness.

All claim limitations must be considered when judging the patentability of the claim against the prior art. MPEP 2143.03. In the Board of Patent Appeals and Interferences decision, In re Wada and Murphy, Appeal No. 2007-3733 (January 14, 2008), the Board reaffirmed that an Examiner cannot skip a claim limitation when rejecting a claim as being obvious. The Board explained that a finding of obviousness requires a suggestion in the prior art of all limitations in the claim.

There are several elements of the independent claims missing from the applied prior art references. The obviousness rejection is therefore improper and should be withdrawn.

The Examiner is also reminded that a means-plus-function claim element requires examination pursuant to 35 U.S.C. §112, 6th paragraph and MPEP 2181. This requires a two-step process. First, to find a means-plus-function claim limitation in a prior art reference, the asserted prior art must include the means or step for performing the function specified in the claim. Second, the asserted prior art must also include the structure from Applicant's specification (or equivalent structure) for implementing the claimed function. MPEP 2181, see also *In re Donaldson Company*, 16 F3d 1189, 1193 (Fed. Cir. 1994), and *Fresenius USA, Inc. v. Baxter International, Inc.*, 582 F3d 1288, 1299 (Fed. Cir. 2009). With respect to the means-plus-function claim element in the amended independent claims, the applied prior art fails on both accounts. The applied art does not identify either the recited function or any structure that could implement the recited function.

**Howorth Does Not Disclose Claimed Features**

The Howorth '956 patent has been applied as the primary reference. Fig. 2 from the Howorth '956 patent is reproduced below.

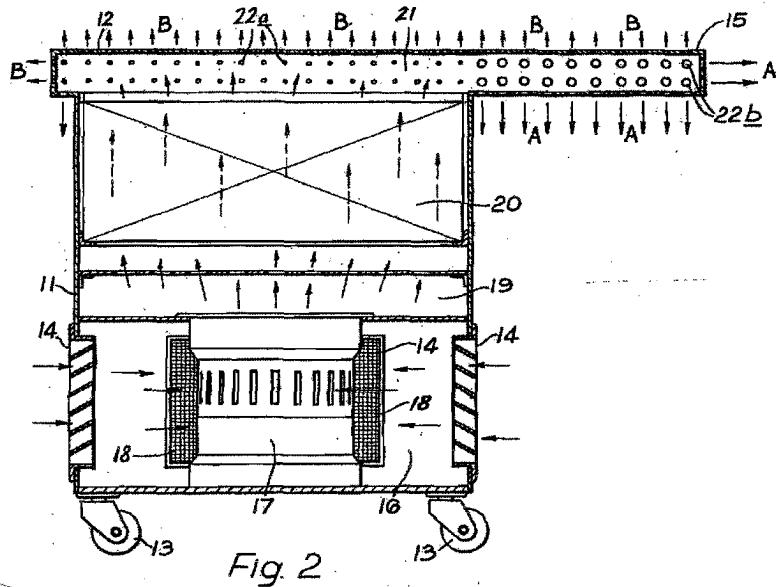


Fig. 2

In the Howorth '956 patent, sterile air exits vertically upward from the work surface of the trolley as well as outward from the edges of the work surface and downward from a portion of the

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work surface. Comparing the disclosure in Howorth to the language of the independent claims, the Howorth '956 patent does not contain at least the following claim limitations: 1) means for giving rise to a continuously replenished rising layer of filtered air over the work surface and forming a robust blanket of sterile air over the work surface; 2) an upstanding boundary wall extending around the perimeter of the work surface whereby the work surface and the boundary wall form a tray; 3) the boundary wall being hollow and extending fully around the perimeter of the work surface; 4) directing filtered air into the boundary wall and emitting the filtered air through outlets in the boundary wall facing inwardly of the boundary wall over the work surface from opposing sides; and 5) a boundary wall comprising first and second pairs of opposing straight parallel sidewalls such that filtered air is emitted inwardly over the work surface from opposing straight parallel sidewalls in use.

Aside from pointing out the complete absence of these claim limitations in Howorth, Applicant would also like to point out the analysis in paragraph 4 of the Office Action dated November 20, 2009 contains errors. First, while the Examiner is accurate in stating that the Howorth '956 patent has a work surface consisting essentially of air outlets, this feature is not a feature of the independent claims. In fact, the specification and drawings of the present application describe the work surface as not containing air openings. Paragraph [0034] of the specification specifically states that it is not desirable to have air apertures directed upwardly.

Second, paragraph 4 in the Office Action indicates that Howorth discloses filtered air emitting inwardly over the work surface from the sidewalls, and cites Col. 2, lines 24-28, as evidentiary basis for this finding. The citation and finding are a mistake. The citation appears to be a citation from the Marsh reference. The Howorth system does not emit filtered air inwardly over the work surface from a sidewall. It does not even have a sidewall.

#### **Marsh Does Not Disclose Claimed Features**

Comparing the disclosure in Marsh to the language of the independent claims, the Marsh '999 patent does not contain at least the following claimed limitations: 1) means for giving rise to a continuously replenished rising layer of filtered air over the work surface and forming a robust blanket of sterile air over the work surface; 2) a hollow boundary wall extending fully around the perimeter of the work surface; 3) a hollow boundary wall comprising first and second pairs of opposing straight

parallel sidewalls; and 4) directing filtered air into the hollow boundary wall and emitting the filtered air through outlets in the boundary wall facing inwardly of the boundary wall over the work surface from opposing straight parallel sides.

As previously discussed, the Marsh reference uses an annular diffuser to pass filtered air into its central well and create a rising vortex. Col. 2, lines 63-69 of the Marsh '999 patent explains:

The diffuser expands under the influence of the air flow directed therethrough and discharges a uniform mass of air in a 360° arc towards the center of the diffuser well. As the rushing masses of air collide, they form a vertically rising vortex....

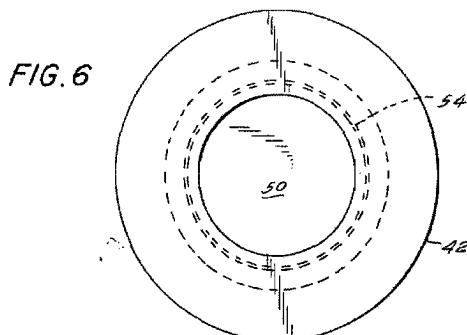
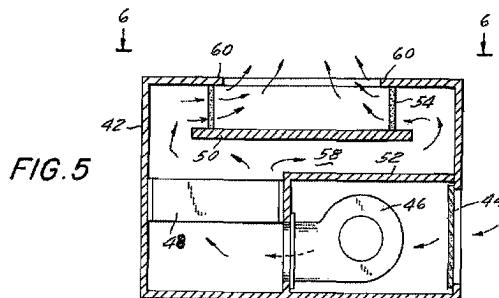
Marsh et al., at Col. 1, lines 19-24, make clear that their invention is not a laminar flow workbench. The air exiting the diffuser 54 is "diffused" meaning that it is not a laminar or layered flow. In fact, lip 60 on the top of the housing chamber is needed to guide the outpouring of air and prevent immediate expansion of the air from the diffuser. The diffused flow of air and the rising vortex from the annular diffuser in the Marsh '999 patent is quite different than the claimed invention which "gives rise to a continuously replenished rising layer of filtered air over the work surface to form a robust blanket of sterile air over the work surface". Neither Marsh, nor Howorth, discloses this claimed function or any structure that would be sufficient to implement the claimed function.

The Marsh patent describes the annular diffuser as being made from reticulated flexible foam having about 45 to 100 pores/sq. in. Marsh suggests that, alternatively, the diffuser may be fabricated from a filtration media, Marsh Col. 3, lines 73-74. Nowhere does Marsh suggest that the "diffuser" could consist merely of a hollow wall having air outlets facing inwardly over the work surface. Of course, such structure would frustrate the purpose of the "diffuser" in Marsh which is to diffuse the air flow. Neither Marsh, nor Howorth, discloses or suggests a hollow wall having air outlets facing inwardly over the work surface.

Of course, the annular diffuser in Marsh is designed specifically to create a rising vortex, and it is legally improper to infer that Marsh somehow suggests a rectangular, hollow boundary wall. The diffuser in Marsh is annular so that it creates a rising vortex. The claimed structure on the other hand requires that the hollow boundary wall comprise first and second pairs of opposing straight

parallel sidewalls. The claimed structure does not create a rising vortex. The Examiner's proposed modification to Marsh would improperly change the principle of operation of the annular diffuser in Marsh. See, MPEP 2143.01.

Respectfully, the combination of Howorth and Marsh would most likely result in a system similar to that disclosed in Figs. 5 and 6 of Marsh. In other words, when applying the invention in Marsh for use on sterile air trolley, one of ordinary skill in the art would maintain the annular shape of the diffuser and its rising vortex as depicted in Figs. 5 and 6 of Marsh.



The Examiner is reminded that impermissible hindsight must be avoided and that the legal conclusion of obviousness must be reached on the basis of facts gleaned from the prior art. MPEP 2142. Since, several of the elements of the claims are not disclosed or suggested by the applied prior art, the obviousness rejection should be withdrawn.

**New Dependent Claims**

Applicant submits that new dependent claim 22 is novel and inventive in light of the prior art, for reasons separate and apart from the reasons expressed above with respect to the independent claims. Claim 22 recites that the upstanding boundary wall does not have an inwardly projecting lip. Such a claim limitation is proper under MPEP 2173.05(i). Claim 22 has basis from the specification as filed, for example from figure 2, which clearly shows that the upstanding boundary wall 13 does not have an inwardly projecting lip.

Howorth does not disclose apparatus having an upstanding boundary wall, therefore Howorth is not relevant for consideration of patentability of claim 22. Marsh discloses apparatus having an upstanding diffuser, however the diffuser has a radially, inward projecting lip on the superior edge of the inner periphery of the diffuser (see col. 1, lines 35-45; col. 2, lines 38-44; col. 3, lines 26-30). The lip of Marsh (feature 38 in figure 4 and 60 in figure 5) "prevent[s] the immediate expansion of air as it diffuses into the central well [and] in order to give direction to the outpouring of air from the diffuser". In the apparatus of Marsh, the air being directed in a 360° arc inwardly from the diffuser causes a vertically rising vortex of air to form (see col. 2, lines 63-69); the lip prevents immediate expansion of the turbulent vortex of air (see col. 2, lines 38-42) and creates more turbulence in the rising vortex of air.

Unlike the apparatus of Marsh, the invention of claim 22 does not have an inwardly projecting lip on the upstanding boundary wall. The apparatus of the claimed invention gives rise to a continuously rising layer of air over the work surface that forms a robust blanket of sterile air over the horizontal work surface. If an inwardly projecting lip were present on the superior edge of the inner periphery of the boundary wall of the apparatus of the present invention, and if the lip were large enough, the lip would disturb the rising layer of sterile air thereby compromising the protection offered to surgical tools on the work surface. It would not have been obvious in light of the prior art to provide apparatus having an upstanding boundary wall without an inwardly projecting lip as Marsh teaches. The omission of a lip on the boundary wall goes against the teaching of Marsh. Therefore, the invention of claim 22 is novel and inventive.

Applicant also submits that new claim 23 is novel and inventive in light of the prior art for reasons separate and apart from the reasons expressed above with respect to the independent claims. Claim 23 recites that the boundary wall is densely perforated with many substantially uniformly distributed apertures to provide a substantially uniform flow of air through the boundary wall. This has basis from the specification as filed, for example from page 4, lines 24-27 and claim 10. The Examiner contends that a sterile trolley having the features of claim 1 and a boundary wall that is densely perforated with many substantially uniformly distributed apertures to provide a substantially uniform flow of air through the boundary wall is obvious in light of Howorth and Marsh, as Marsh discloses a work tray comprising boundary walls which are densely perforated. However, the Applicant respectfully disagrees. The diffuser of Marsh is disclosed as being made of reticulated, flexible foam, particularly reticulated polyurethane foam (see col. 2, lines 34-37). The pores of reticulated foam would not be uniformly distributed within the foam, as recited by claim 23, and would not be of uniform size, and therefore would not provide a substantially uniform flow of air through the boundary wall. The diffuser of Marsh is designed to "diffuse" the air emitted from it; in other words, the diffuser scatters the air emitted from it, rather than providing a uniform flow of air, as recited by claim 23.

It would not have been obvious to provide a trolley with a boundary wall that is densely perforated with many substantially uniformly distributed apertures to provide a substantially uniform flow of air through the boundary wall as described in connection with the present invention. The apparatus of Howorth has apertures distributed over the top of the work surface, the apertures being directed upwardly. The apparatus of Marsh has a diffuser made of reticulated foam directing air inwardly over the work surface; however the pores in the reticulated foam diffuser are not uniformly distributed. A person of ordinary skill trying to combining the teaching of Howorth and Marsh would not produce an invention having the features of claim 23. Instead, they might produce a trolley having apertures directed upwardly from the work surface and a circular boundary wall having non-uniformly distributed pores in a reticulated foam diffuser in a boundary wall. For these reasons, the invention of claim 23 is novel and inventive in light of the prior art.

**Pending Dependent Claim 5**

With regard to claim 5, the Examiner contends it would have been obvious to provide the trolley of Howorth with an upper unit comprising a tray-shaped work surface with a boundary wall, the upper unit being readily demountable from and re-mountable with a base unit. We respectfully submit that claim 5 is novel and inventive in light of the prior art. There is no disclosure in Howorth that an upper unit comprising a work surface should be demountable from the base unit. Nor would it have been obvious from Howorth in light of Marsh that a tray-shaped work surface and boundary wall of the trolley of Howorth should be readily demountable from a base unit. In Marsh, the boundary wall is either not attached to a work surface (as in the embodiment of figures 3 and 4, wherein the diffuser is simply placed over a target area) or the boundary wall is integral with a work surface (as in the embodiment of figure 5). It would not have been obvious from Marsh to provide the trolley of Howorth with a boundary wall that is readily demountable, as part of an upper unit also comprising a work surface, from a base unit. An advantage of providing an upper unit comprising a work surface and boundary wall wherein the upper unit is demountable from the base unit is that the upper unit can be sterilized in an autoclave, such that the work surface and the surgical instruments on the work surface can be sterilized alongside each other, to facilitate preparation of the equipment prior to a surgical operation (see page 3, lines 27-33).

It would not have been obvious from Marsh that by providing an upper unit comprising a boundary wall and work surface wherein the upper unit is demountable from a base unit, this would be advantageous for sterilizing the work surface and surgical instruments together. The upper unit of the present invention can be sterilized in an autoclave; autoclaves typically sterilize equipment by subjecting them to high pressure steam at 121°C or more. It is known that polyurethane foam has a poor response to steam sterilization from autoclaves, and polyurethane foam is likely to be damaged by the high temperature steam in an autoclave. Therefore, even if a person of ordinary skill were to provide the trolley of Howorth with an upper unit having a work surface and a diffuser like that of Marsh, they would not be motivated to make the upper unit demountable for sterilization as the reticulated polyurethane foam of the diffuser of Marsh would not be properly sterilized by an autoclave,

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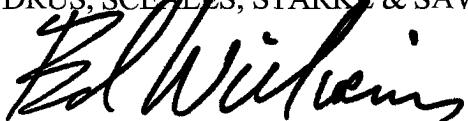
and may suffer damage from the high temperature steam in an autoclave. For these reasons, the invention of claim 5 is novel and inventive in light of the prior art.

**Conclusion**

Applicant appreciates the Examiner's attentiveness and respectfully requests that the application as amended be allowed to issue.

Respectfully submitted,

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